# In the United States Court of Federal Claims

#### **OFFICE OF SPECIAL MASTERS**

Reissued for Public Availability Date: June 1, 2023

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NADINE LYNN McLEE,	*	
,	*	No. 20-1283V
	*	
Petitioner,	*	Special Master Christian J. Moran
	*	•
V.	*	Filed: May 10, 2023
	*	•
SECRETARY OF HEALTH	*	Entitlement; shoulder injury
AND HUMAN SERVICES,	*	related to vaccine administration
	*	("SIRVA"); influenza ("flu") vaccine.
Respondent.	*	
* * * * * * * * * * * * * * * * * * *	* *	

<u>Nadine Lynn McLee</u>, *pro se*, Pittsburgh, PA, for petitioner; <u>Katherine C. Esposito</u>, United States Dep't of Justice, Washington, D.C., for respondent.

# <u>UNPUBLISHED RULING DENYING</u> <u>COMPENSATION ON TABLE CLAIM</u><sup>12</sup>

Nadine McLee alleged that the trivalent influenza ("flu") vaccine she received on September 27, 2017, caused her to suffer left shoulder injuries. Amended Pet., filed Mar. 3, 2021, at Preamble, ¶¶ 2-4. The information in the

<sup>&</sup>lt;sup>1</sup> Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <a href="https://www.govinfo.gov/app/collection/uscourts/national/cofc">https://www.govinfo.gov/app/collection/uscourts/national/cofc</a>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted in the website.

<sup>&</sup>lt;sup>2</sup> Pursuant to Vaccine Rule 18(b), this Ruling was initially filed on May 10, 2023, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly., this Ruling is reissued in its original form for posting on the Court's website.

record, however, does not support Ms. McLee's allegation of a Table shoulder injury related to vaccine administration ("SIRVA").

Ms. McLee's SIRVA claim suffers from three problems. First, Ms. McLee has not shown that her injury occurred within 48 hours of vaccination. Exhibit 3 at pdf 1, 7. Second, although Ms. McLee claims an injury to her *left* shoulder, the medical records show that Ms. McLee received the flu vaccine in her *right* deltoid. Exhibit 2A at pdf 1. Third, Ms. McLee has not shown that her pain was limited to the left shoulder. CM/ECF 18-2 at pdf 19; Exhibit 8 at pdf 1. Ms. McLee has therefore failed to establish that she meets the criteria for a SIRVA claim, and thus, this claim is dismissed. However, Ms. McLee may proceed with her claim alleging an off-Table shoulder injury.

#### **I.** Summary of the Evidence

#### A. Medical Records Before Vaccination, Including Vaccination

Ms. McLee was born on May 1, 1960. Exhibit 1 at pdf 1. She is left-hand dominant. Exhibit 3 at pdf 1. At the time of vaccination, Ms. McLee worked full time as a patient information coordinator at the University of Pittsburgh Medical Center ("UPMC") Passavant Cranberry, a job that requires frequent typing. CM/ECF 18-2 at pdf 4; Exhibit 5 at pdf 27.

On September 27, 2017, Ms. McLee visited Dr. Farrell for a pre-operative evaluation for a cataract surgery scheduled for October 6, 2017. CM/ECF 18 at pdf 38. Dr. Farrell noted no issues nor any need to take special precautions with respect to the upcoming cataract surgery. <u>Id.</u> at pdf 41. He discussed the cessation of smoking with Ms. McLee and asked for a six-month follow up. <u>Id.</u>

During her visit with Dr. Farrell on September 27, 2017, Ms. McLee received the flu vaccine. CM/ECF 20-2; Exhibit 2A at pdf 1. Here, there is a dispute regarding whether Ms. McLee received her flu vaccine in her right or left deltoid. The medical records indicate that Ms. McLee received the flu vaccine in her right deltoid. Exhibit 2A at pdf 1.<sup>3</sup> However, Ms. McLee later complained of

<sup>&</sup>lt;sup>3</sup> Ms. McLee disputes the accuracy of these records and claims she received the vaccine in her left deltoid. Exhibit 5 at pdf 32; CM/ECF 53-2 (Onset Aff.) at pdf 3. In her motion for summary judgment, Ms. McLee asserts the discrepancies "are based on PCP deception." Pet'r's Mot., filed Nov. 5, 2021, at 2. Ms. McLee reports that "a record correction was requested," though it apparently was not

and sought treatment for left arm pain. See, e.g., Exhibit 8 at pdf 1; Exhibit 3 at pdf 1.

#### **B.** Medical Records After Vaccination

1. Medical Records from December 9, 2017 to March 27, 2018

On December 9, 2017, approximately 10 weeks after receiving the flu vaccine, Ms. McLee sought treatment at MedExpress Ross Township Urgent Care for left shoulder pain. CM/ECF 18-2 at pdf 4. The doctor reported limited flexion and extension in Ms. McLee's left shoulder due to pain. <u>Id.</u> Ms. McLee denied any injury and was diagnosed with an unspecified sprain of her left shoulder joint and prescribed prednisone. <u>Id.</u> at pdf 6. The medical records from this visit indicate that Ms. McLee was experiencing "L shoulder pain x 1 month" that was aggravated due to frequent typing at work. <u>Id.</u> at pdf 4. This history implies that Ms. McLee's shoulder pain began around November 9, 2017.

On December 13, 2017, Ms. McLee visited the UPMC emergency room. Exhibit 3 at pdf 1; CM/ECF 17 at pdf 14. The medical records indicate her primary complaint was a "one month history of left arm pain accompanied by intermittent episodes of numbness and tingling." Exhibit 3 at pdf 1. This history suggests the onset of pain was around November 13, 2017. Ms. McLee also stated that she had "perceived weakness in her left hand." Id. She denied any specific injury and stated that her pain extended "from her trapezius along the lateral side of her arm," with the pain being exacerbated by any type of movement. Id. Ms. McLee stated that she began working out with a trainer starting approximately six weeks prior but had not done any exercises that caused the shoulder injury. Id. She denied any trauma besides being on the computer during work. <u>Id.</u> at pdf 4. She described her left arm as feeling heavy and felt a shooting pain when her left shoulder blade, dorsal aspect of the upper left arm, and antiecubitis areas were pressed. Id. At the time of this visit, Ms. McLee had almost finished the steroids she was prescribed on December 9, 2017, and noted that even a high dose of the steroid did not help her pain. Id. at pdf 1. Upon physical examination, Ms. McLee had tenderness in her left trapezius on palpation and a slightly weaker grip on the left side. Id. at pdf 2. Additionally, Ms. McLee experienced a significant increase in pain on her left side while doing a shoulder shrug. Id. She was diagnosed with

granted as no corrections were provided. <u>Id.</u> Ms. McLee "denies responsibility for MD's fake assessment and documentation which disregarded [her] left arm pain." <u>Id.</u>

intractable left cervical radicular pain and transferred to UPMC Passavant McCandless for further evaluation and treatment. <u>Id.</u> at pdf 3.

Later that same day, Ms. McLee was seen by another physician at the UPMC, Dr. Amit, for a spine consultation. Exhibit 3 at pdf 7. The medical records state that she had progressive weakness and pain in the left upper extremity which started in the left scapula, went across the neck and over both biceps and triceps, with numbness in all 5 fingers on the left "over the last 1½ months." Id. This history implies that the onset of Ms. McLee's pain would have been around late October 2017. Ms. McLee denied symptoms in her right upper extremity. Id. Upon musculoskeletal examination, Ms. McLee could not abduct more than 15 degrees on the left upper extremity. Id. at pdf 8. Because Ms. McLee's condition had not improved with oral prednisone or IV solumedrol, Dr. Amit prescribed Robaxin for pain control. Id. at pdf 10.

On December 14, 2017, Ms. McLee reported back to the University of Pittsburgh Medical Center with worsening pain with range of motion of the left arm. Exhibit 3 at pdf 25. Ms. McLee was tender to palpation of the left trapezius area and had occasional tingling and numbness in her left arm. <u>Id.</u>

The next day, on December 15, 2017, Ms. McLee was ordered to undergo a brain MRI exam with and without contrast. Exhibit 3 at pdf 13. The purpose of the exam was to rule out a stroke. <u>Id.</u> The impression was no acute intracranial abnormality, meaning no acute stroke. <u>Id.</u> That same day, Ms. McLee told Dr. Shtrahman, a neurologist, that she was feeling better. <u>Id.</u> at pdf 23. Dr. Shtrahman diagnosed Ms. McLee with "[1]eft upper extremity pain and 'weakness'" and noted that the workup thus far had been unremarkable. <u>Id.</u> For next steps, Dr. Shtrahman recommended an EMG and nerve conduction studies. <u>Id.</u> Ms. McLee was stable for discharge. <u>Id.</u>

Ms. McLee saw Dr. Farrell again on January 3, 2018. Exhibit 5 at pdf 25. The medical records show that she informed him that weakness in her left arm "ha[d] been developing slowly since October" of 2017. <u>Id.</u> At the time of this visit, Ms. McLee had no symptoms on her right side or neck. <u>Id.</u> Dr. Farrell noted that there was no acute trauma or injury. <u>Id.</u> Ms. McLee's left side presented with tenderness in the left trapezius ridge and her range of motion on the left shoulder was restricted. <u>Id.</u> Dr. Farrell indicated that Ms. McLee had impingement syndrome of the left shoulder. <u>Id.</u> He noted that her grip strength on the left side was maybe just a little weaker, especially considering that Ms. McLee is left-

handed. <u>Id.</u> Dr. Farrell referred her to an orthopedist to give her a prescription for physical therapy. <u>Id.</u>

On January 16, 2018, Ms. McLee visited orthopedist Dr. Gause. CM/ECF 18-2 at pdf 18. Dr. Gause's notes state that Ms. McLee is right-hand dominant<sup>4</sup> and presented for evaluation of the left shoulder. <u>Id.</u> The records indicate that Ms. McLee reported that the onset of her pain "2 months ago on 11/20/17 after receiving a flu shot." <u>Id.</u> The records further state that her pain was "localized somewhat diffusely about her neck traveling into the left trapezius and anterolateral aspect of her left shoulder." <u>Id.</u> Ms. McLee reported a "constant achy pain" as well as "numbness in her fingers" and "some decreased range of motion and weakness." Id.

On January 24, 2018, Ms. McLee had her first visit with physical therapist Matthew Sennott. CM/ECF 20-8 at pdf 7. The date of onset was reported as September 18, 2017. <u>Id.</u> at pdf 12. Ms. McLee stated that she had "increased muscle pain in her l[eft] shoulder following a flu shot in September 2017." <u>Id.</u> The pain, as Ms. McLee described, progressed like a toothache. <u>Id.</u> Mr. Sennott noted that Ms. McLee is left-hand dominant and worked a desk job that required a lot of time typing and writing. <u>Id.</u> The next day, on January 25, 2018, Ms. McLee had an MRI performed on her left shoulder. <u>Id.</u> at pdf 29. There were no significant derangements in the left shoulder. CM/ECF 28 at pdf 35.

Ms. McLee saw Dr. Esman on January 29, 2018, for left upper extremity pain. CM/ECF 18-2 at pdf 19-20. Dr. Esman noted that Ms. McLee was left-hand dominant and presented with a four-month history of pain in her left upper arm, along with tingling and numbness in her forearm and fingertips. <u>Id.</u> This history suggests that the onset of pain began approximately on September 29, 2017. Ms. McLee also believed the problem started after getting her flu shot. <u>Id.</u> Dr. Esman found that Ms. McLee had diffuse mild weakness throughout the left upper extremity. <u>Id.</u> Nerve studies were performed, and the nerve conduction portion was normal and showed no evidence of carpal tunnel syndrome or ulnar neuropathy or any evidence of impairment of sensory amplitudes as would be seen in a brachial plexus lesion. <u>Id.</u>

<sup>&</sup>lt;sup>4</sup> This appears to be incorrect because the medical records consistently indicate that Ms. McLee is left-hand dominant. See, e.g., CM/ECF 18-2 at pdf 19; CM/ECF 20-8 at pdf 7; Exhibit 3 at pdf 1; Exhibit 5 at pdf 25, 27.

On February 2, 2018, Ms. McLee saw Dr. Gause again. CM/ECF 18-2 at pdf 28-29. Dr. Gause's notes state that Ms. McLee was bothered by diffuse neck pain traveling into her left shoulder and arm. <u>Id.</u> at pdf 21. Dr. Gause concluded that at this point, he could not find an etiology for her symptoms and recommended that Ms. McLee follow up with her primary care physician. <u>Id.</u> at pdf 29. Additionally, that same day, Ms. McLee had physical therapy with Matthew Sennott. CM/ECF 20-8 at pdf 4. Mr. Sennott noted that Ms. McLee had continued soreness in her left shoulder, which she said was so bad that it was numbing at times. <u>Id.</u> Ms. McLee also said that typing all day at work had increased her symptoms. <u>Id.</u> She was subsequently discharged from physical therapy on March 9, 2018, likely because she was too busy working to attend the sessions. CM/ECF 20-8 at pdf 17; Exhibit 8 at pdf 1.

On a follow up visit to Dr. Farrell on February 6, 2018, Ms. McLee described her left shoulder pain as beginning in mid-September 2017. Exhibit 5 at pdf 27. He noted that her pain continued in the same place and severity as the last time he saw her. <u>Id.</u> Ms. McLee explained that her sleep was disturbed due to the pain so she could not sleep on her back, and instead needed to sleep right laterally recumbent. <u>Id.</u> However, the pain was not deep aching and Ms. McLee was not noticing motor weakness. <u>Id.</u> He noted that she is left-handed and was working as a clerical person checking inpatient stay at UPMC Passavant Cranberry and had not missed work due to the pain. <u>Id.</u> Dr. Farrell explained that her range of motion of the shoulder was limited in elevation extension, and that it would be helpful if Ms. McLee could tolerate nerve conduction studies. <u>Id.</u> He suggested a referral to Dr. Cheryl Bernstein for neurology and pain medicine and prescribed Cymbalta. <u>Id.</u> at pdf 27-28.

On March 27, 2018, Ms. McLee visited UPMC Pain Medicine and saw Dr. Bernstein. CM/ECF 28 at pdf 40. Ms. McLee's chief complaints were arm and hand pain, with an onset date reported as September 17, 2017. <u>Id.</u> at pdf 40, 52. Dr. Bernstein diagnosed Ms. McLee with chronic pain syndrome and found that there were no significant internal derangements in the left shoulder. <u>Id.</u> at pdf 40, 45. Ms. McLee was referred to an occupational therapist and a physical therapist, as well as referred for a psychological evaluation for her chronic pain syndrome. <u>Id.</u> at pdf 47.

#### 2. Medical Records from April 6, 2018 to November 13, 2018

Ms. McLee had a follow up appointment with Dr. Farrell on April 6, 2018, for chronic pain from the anterior shoulder distal to the hand with paresthesia

without diagnosis. Exhibit 5 at pdf 28-29. Dr. Farrell noted that there had been no change in pain intensity, character, or location, or pain at new sites since he last saw Ms. McLee. <u>Id.</u> Additionally, Ms. McLee's range of motion of the shoulder was limited. <u>Id.</u> He referred her for another orthopedic opinion at Western Pennsylvania Hand and Upper Extremity Center. <u>Id.</u>

On April 27, 2018, Ms. McLee was evaluated by Dr. Balk at the Hand and Upper Extremity Center. Exhibit 8 at pdf 1. Ms. McLee's primary complaints were of left upper arm pain and stiffness and left-hand numbness, which she attributed to a flu vaccine from September 2017. <u>Id.</u> She expressed that she had a constant throbbing pain in her left upper arm that sometimes radiated to her neck. <u>Id.</u> Dr. Balk noted that Ms. McLee was prescribed physical therapy but could not attend because of a busy work schedule. <u>Id.</u> He recommended more physical therapy as well as a cortisone injection, which Ms. McLee declined. <u>Id.</u> at pdf 3. Additionally, Dr. Balk expressed the importance of a nerve conduction study for Ms. McLee's complaints of hand numbness. <u>Id.</u>

On May 8, 2018, Ms. McLee again visited Dr. Bernstein for arm and hand pain. CM/ECF 28 at pdf 30. Ms. McLee was scheduled for a repeat EMG/NCS of the left upper extremity because she could not tolerate the EMG the first time. <u>Id.</u> Ms. McLee had not had much relief from her pain, mostly because she could not attend physical therapy appointments due to her work schedule. <u>Id.</u> On physical examination, Ms. McLee could not actively get past 45 degrees abduction on the left side. <u>Id.</u> at pdf 34. Dr. Bernstein suggested that Ms. McLee consider a shoulder injection, suprascapular nerve block, to improve her range of motion without pain. <u>Id.</u> at pdf 36.

Ms. McLee revisited Matthew Sennott on May 10, 2018, for physical therapy for chronic left shoulder pain. CM/ECF 20-9 at pdf 23. He noted that she was experiencing difficulty with activities of daily living, including active shoulder motion, dressing, and driving. Id. at pdf 28. Additionally, Ms. McLee had been having trouble with work duties, including keyboarding, writing, and using the phone. Id. On May 15, 2018, she returned to physical therapy and reported that she had continued pain and was having trouble sleeping because she was unable to find a comfortable position. Id. Ms. McLee did not tolerate the session well, and reported increased pain with any motion at or about 90 degrees. Id. at pdf 42-43. Ms. McLee had another session with Mr. Sennott on May 17, 2018, and reported continued soreness and intermittently completing her home exercise program. Id. at pdf 48. She had good tolerance to this session and completed progressions with minimal soreness. Id. She reported for a final session on May 24, 2018, and was

subsequently discharged with a recommendation for an independent home program. <u>Id.</u> at pdf 54-56.

On August 13, 2018, Ms. McLee visited the emergency room due to abdominal pain, nausea, and diarrhea. CM/ECF 17 at pdf 7. Additionally, Ms. McLee noted she had chronic left arm pain for the last year since her flu shot but had seen a specialist and was taking ibuprofen to manage the pain. <u>Id.</u> The doctor also noted blood in her urine, which he treated as a urinary tract infection and recommended she see a urologist in two weeks if the bleeding in her urine did not subside. <u>Id.</u> at pdf 8. Ms. McLee was formally diagnosed with abdominal pain, hematuria with concern for urinary tract infection, and elevated systolic blood pressure without a history of hypertension. <u>Id.</u>

The next day, on August 14, 2018, Ms. McLee had a follow up visit with Dr. Farrell. Exhibit 5 at pdf 29. He explained to her that her pain seemed like a chronic problem and that they needed to work to try to suppress her pain. <u>Id.</u> at pdf 30. The medical records reflect that Ms. McLee thought her left arm was getting weaker. <u>Id.</u> She noted that she had exercises that she learned from physical therapy, but Dr. Farrell mentioned that he did not think she was doing the exercises regularly. <u>Id.</u> He raised her dosage of Cymbalta and recommended she revisit Dr. Bernstein to discuss the possibility of a nerve block. <u>Id.</u>

On November 23, 2018, Ms. McLee returned to Dr. Bernstein for continued left arm pain. CM/ECF 28 at pdf 22, 26. She reported pain in her "left neck, shoulder, and arm," and reported that her "fingers are always numb" and "bicep is a constant toothache." <u>Id.</u> at pdf 23. Ms. McLee was to undergo a repeat EMG, but she stated that she did not want to do so despite having continued numbness and tingling. <u>Id.</u> at pdf 22, 26. Further, the records reflect that Ms. McLee did not believe the Cymbalta was improving her pain. <u>Id.</u> The attending noted neuropathic pain and recommended that Ms. McLee increase her dosage of Cymbalta and consider nortriptyline. <u>Id.</u> at pdf 26.

# 3. Medical Records from February 19, 2019 to April 2, 2021

Ms. McLee reported for a radiology consultation on February 19, 2019, for congestion, productive cough, and body aches for ten days. CM/ECF 28 at pdf 8. She received a chest x-ray and was diagnosed with bronchitis. <u>Id.</u>; CM/ECF 18-2 at pdf 3. She was prescribed benzonatate, prednisone, ventolin, and an inhaler. CM/ECF 18-2 at pdf 3.

On August 13, 2019, Ms. McLee went to MedExpress because of swelling in her right shoulder after a flu shot two years ago. CM/ECF 18-2 at pdf 10. She reported tingling and numbness, and stated she had been careful with it since. She also reported pain around the scapula. <u>Id.</u> She was diagnosed with a sprain of the ligaments of the thoracic spine and was prescribed prednisone and cyclobenzaprine. <u>Id.</u> at pdf 11.

No other relevant medical records have been filed.<sup>5</sup>

#### C. Affidavits<sup>6</sup>

Ms. McLee completed an onset affidavit, which was initially filed on March 30, 2022. CM/ECF 53-2 (Onset Aff.). Ms. McLee claims that her left shoulder pain began immediately "upon needle stick" and describes the pain as "shocking, continuous, [and] expansive." <u>Id.</u> at pdf 2. She states that the part of her shoulder that was affected was "the injection site area and beyond." <u>Id.</u> She claims that she could not lift her arm above her shoulder and felt like her arm was paralyzed. <u>Id.</u> Ms. McLee claims that during her appointment on September 27, 2017, she "immediately" informed the nurse who administered the vaccine, Kala Cinker, that she was experiencing shoulder pain. <u>Id.</u> Additionally, Ms. McLee states that she had difficulty sleeping later that night due to constant repositioning in her bed,

<sup>&</sup>lt;sup>5</sup> Ms. McLee filed additional materials in CM/ECF 42, including records regarding a cataract surgery on October 6, 2017; COVID vaccination records; records from visits to the UPP Department of Dermatology and Specialists in Plastic Surgery of Pittsburgh regarding a mass in Ms. McLee's upper right arm; and records from UPMC Heart and Vascular Institute. However, CM/ECF 42 was stricken from the record because it contained multiple filings which were not properly labeled as exhibits. Ms. McLee was ordered to individually refile documents in this filing with clear exhibit headings, but did not do so. <u>See</u> Order, issued Aug. 19, 2022.

<sup>&</sup>lt;sup>6</sup> Affidavits from Ms. McLee's children, Hannah Avva and Bradley McLee Jr., were filed on March 30, 2022 with CM/ECF 42, but were never resubmitted after this filing was stricken from the record. Bradley McLee Jr. stated that he spoke to Ms. McLee the day of her September 27, 2017 vaccination, and Hannah Avva stated that she spoke with Ms. McLee a few days after. Both stated that she told them her pain began immediately.

which she needed help doing. <u>Id.</u> She represents that her full left shoulder area was affected, and she could not lift her arm above her shoulder. <u>Id.</u>

Ms. McLee also disputes the accuracy of certain medical records which state the onset of her pain. The medical records from December 9, 2017 state that Ms. McLee had been experiencing left arm pain for one month, and additional medical records from December 13, 2017 state that Ms. McLee had been experiencing left arm pain for the past one-and-a-half months; however, Ms. McLee denies this and maintains that her entire arm was in pain since September 27, 2017. Id. at pdf 3-4. Similarly, medical records from January 3, 2018, state that Ms. McLee's pain had been developing since October 2017, which she denies saying. Id. Finally, Ms. McLee disputes the medical record from January 16, 2018, which states that she had been experiencing left arm pain since November 20, 2017. Id. at pdf 5.

In an affidavit by Ms. McLee's husband, Bradley McLee Sr., submitted February 3, 2023, Mr. McLee alleges that the medical records are "erroneous" due to "mistakes or lies" on the part of healthcare providers. CM/ECF 53-1 at pdf 2. Specifically, Mr. McLee states that the records showed the "wrong arm", and that "[r]eports of non-injury, right arm, later onset of pain, PCP notes, etc. are preposterous." <u>Id.</u> at pdf 3. He refers to Ms. McLee's "SIRVA" and describes her "pain, loss of motion, [and] weariness." <u>Id.</u>

## **II.** Procedural History

Ms. McLee first filed her petition on September 28, 2020, alleging "injuries, including Guillain Barre Syndrome" and "SIRVA." An initial status conference was held on October 29, 2020. A deadline for the Secretary's Rule 4 report was not set, as Ms. McLee had outstanding records to file. Ms. McLee was ordered to continue collecting her medical records. On March 3, 2021, Ms. McLee filed more medical records and an amended petition, again alleging "injuries, including Guillain Barre Syndrome" and "SIRVA." The Secretary identified more outstanding records and Ms. McLee continued filing records through May 2021. On June 21, 2021, the Secretary filed a status report indicating he would complete medical review of this case by late November 2021.

On November 5, 2021, Ms. McLee moved for summary judgment, requesting compensation for her alleged "SIRVA." Ms. McLee disputed the accuracy of the medical records that show that her left shoulder pain began in October or November 2017, and instead argued that her shoulder pain began upon vaccination. See Pet'r's Mot., filed Nov. 5, 2021, at pdf 2-3. Ms. McLee also

asserted that the nurse incorrectly recorded the arm in which she received the flu vaccine, and she requested a correction of the record. <u>Id.</u>

The Secretary opposed Ms. McLee's motion, arguing that Ms. McLee had neither proven SIRVA nor that her alleged injury was caused-in-fact by the vaccination. The Secretary recommended that compensation be denied. See Resp't's Rep., at 17. Contemporaneously with his report, the Secretary moved to dismiss this case, raising, *inter alia*, an issue of statute of limitations. Id. at 15. Ms. McLee did not file a response to the Secretary's motion.

Ms. McLee requested a status conference, which was held on January 25, 2022. During the status conference, Ms. McLee questioned the accuracy of the medical records and mentioned that she received the COVID-19 vaccine. Subsequently, Ms. McLee was ordered to complete an onset affidavit and file her COVID-19 vaccination record by February 25, 2022. Order, issued Jan. 26, 2022. After being granted an extension of time, Ms. McLee filed the additional requested medical records on March 30, 2022. CM/ECF 42, Pet'r's Med. Records, filed Mar. 30, 3022.

Also contained within Ms. McLee's March 30, 2022 CM/ECF 42 filing was a request for discovery. <u>Id.</u> at pdf 77. Among the inquiries, Ms. McLee requested that the Secretary provide answers to a set of interrogatories. <u>Id.</u> There were also affidavits from Ms. McLee's son and daughter. <u>Id.</u> at pdf 16-19. CM/ECF 42 was later stricken however, for failure to appropriately label the records as exhibits. <u>See</u> Order, issued Apr. 11, 2022; Pet'r's Exhibit List, filed May, 9, 2022; Order, issued Aug. 19, 2022

The undersigned issued an order instructing both parties to file a status report on whether a hearing would be appropriate in light of Ms. McLee's November 5, 2021 motion for summary judgment and the Secretary's November 19, 2021 motion to dismiss. Order, issued July 26, 2022. After Ms. McLee's husband contacted chambers seeking information on her right to appeal after electing to close the record, the undersigned ordered both parties to review Ms. McLee's discovery request and to file a status report on the appropriateness of providing answers to the questions. Order, issued Aug. 19, 2022. The undersigned also ordered respondent to review Ms. McLee's discovery request and file a status report on the appropriateness of providing answers to the questions. Id. at 2. Ms. McLee was ordered to refile the non-duplicative exhibits from CM/ECF 42 individually and instructed that she may file an affidavit from her husband

describing his observations of Ms. McLee's vaccination by November 17, 2022. Id.

The Secretary maintained that a hearing was not appropriate in this case. Resp't's Status Rep., filed Sept. 1, 2022. The Secretary also responded to the request for discovery, arguing that petitioner's questions were "overly broad" and were not appropriate for a substantive response. Resp't's Status Rep., filed Sept. 19, 2022. The Secretary's counsel further noted that neither he, HHS, nor DICP had contacted petitioner's former doctor without disclosure. <u>Id.</u> at 2.

Ms. McLee did not submit a filing regarding her position on whether a hearing was appropriate. Ms. McLee did not file an affidavit by the deadline, nor did she refile the exhibits specified in the August 19, 2022 order. It appeared that Ms. McLee had attempted to communicate with a person whose employment within the Office of Special Masters had ended, and so the undersigned, sua sponte, extended the deadline for the exhibits and affidavit to January 26, 2023. Order, issued Dec. 28, 2022. Ms. McLee contacted chambers and the undersigned's law clerk the week of the deadline to inform of an intent to file these materials, but did not file anything. Ms. McLee also did not file a status report detailing why she failed to file these materials. The undersigned, sua sponte, extended the deadline to February 3, 2023, reminding Ms. McLee to file through the CM/ECF system. Order, issued Jan. 27, 2023. On February 3, 2023, Ms. McLee filed an affidavit from her husband, and refiled her affidavit about the onset of her symptoms. CM/ECF 53-1, 53-2.

The Secretary has not filed any materials since his September 19, 2022 status report.

Accordingly, Ms. McLee's SIRVA claim is now ready for adjudication.

#### III. Standards for Adjudication

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa-11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. <u>Cucuras v. Sec'y of Health & Hum. Servs.</u>, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records may not always list all problems a person is experiencing. <u>See Kirby v. Sec'y of Health & Hum. Servs.</u>, 997 F.3d 1378, 1382 (Fed. Cir. 2021).

Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1).

Vaccine Rule 8(d) provides that a "special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." Special masters are required to determine whether hearings or witness testimony are reasonable and necessary. 42 U.S.C. § 300aa-12(d)(3)(B). In doing so, special masters must "afford[] each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision." Vaccine Rule 3(b)(2).

Special masters have previously resolved factual disputes regarding the site of vaccination without conducting a hearing. In <u>Kabelitz</u>, the petitioner argued that affidavits supported the onset of symptoms beginning within 48 hours of vaccine administration. <u>See Kabelitz v. Sec'y of Health & Hum. Servs.</u>, 2022 WL 909055, at \*13 (Fed. Cl. Spec. Mstr. Feb. 17, 2022). However, respondent maintained that the medical histories did not place the onset of symptoms within 48 hours. <u>Id.</u> The special master found which arm a vaccine was administered into without a hearing when "the parties agreed a ruling on the factual issues [wa]s necessary [and] . . . consented to a fact ruling on the record in the absence of a hearing." Id. The

special master gave greater weight to the medical records, noting specifically that the petitioner's affidavit was created approximately one-and-a-half years after the vaccine. <u>Id.</u> at \*18. He ultimately found that petitioner did not provide evidence showing more likely than not that she experienced pain within 48 hours of receiving the vaccine. <u>Id.</u> at \*19.

In <u>Schmidt</u>, the petitioner alleged a left shoulder injury; however, the contemporaneous medical records from the date of vaccination showed that the vaccine was administered in the right arm. <u>Schmidt v. Sec'y of Health & Hum. Servs.</u>, No. 17-1530V, 2021 WL 5226494, at \*1 (Fed. Cl. Spec. Mstr. Oct. 7, 2021). No hearing was held since the petitioner requested a resolution through briefing. <u>Id.</u> at \*2. The special master stated that although "the Petitioner may honestly believe that he received the vaccine alleged as causal in his left arm, the record as it now stands preponderantly supports the opposite." <u>Id.</u> at \*11. As such, the special master concluded that the vaccine was more likely than not administered in petitioner's right arm, as supported by the vaccine administration records. <u>Id.</u>

In <u>Hanna</u>, the parties also disputed the location of petitioner's vaccination site under a SIRVA claim. <u>Hanna v. Sec'y of Health & Hum. Servs.</u>, 2021 WL 3486248, at \*1 (Fed. Cl. Spec. Mstr. 2021). The special master then issued an order requesting that the parties "file a joint status report indicating whether the parties wanted any additional opportunity to develop the record." <u>Id.</u> at \*2. The parties then responded that "neither party request[ed] any further opportunity to develop the record with regard to the site of petitioner's injection. Petitioner request[ed] an opportunity to brief the issue of injection site before the Special Master rules on this issue. Respondent ha[d] no objection to petitioner's request." <u>Id.</u> (internal citation omitted). Thereafter, the special master found it appropriate to resolve the case without a hearing after finding that the parties "had full and fair opportunity to present their cases." <u>Id.</u> at n.3

A ruling on the record differs from adjudicating a motion for summary judgment. <u>Duncan v. Sec'y of Health & Hum. Servs.</u>, 153 Fed. Cl. 642, 656 (2021) (noting that "[i]n *Kreizenbeck*, the Federal Circuit rejected the petitioners' argument that, in light of their objection to a ruling on the record, the special master was obliged to either hold a hearing or resolve their case on summary judgment . . . [and that] the language of the Vaccine Act does not 'suggest[] a consent-based limitation on a special master's authority to rule on the record."") (internal citation omitted). Thus, although the parties here initially presented the case as a motion for summary judgment (Ms. McLee) or a motion to dismiss (the

Secretary), the July 26, 2022 order alerted the parties to a final chance to submit their evidence and arguments. Thus, the standards for motion for summary judgement and motion to dismiss do not govern the present adjudication.

Pursuant to these standards for determining when and whether events did or did not happen, the undersigned finds how the evidence preponderates. In setting forth the findings, the undersigned also cites to the primary evidence that is the basis for the finding. The undersigned recognizes that not all evidence is entirely consistent with these findings. See Doe 11 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (ruling that the special master's fact-finding was not arbitrary despite some contrary evidence).

#### IV. Analysis of SIRVA

To receive compensation under the National Vaccine Injury Compensation Program (hereinafter "the Program"), petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to her vaccination, or (2) that she suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Ms. McLee asserts a "Table Injury" via her SIRVA claim and does not appear to allege the injury was caused-in-fact by the vaccination. Amended Pet., filed Mar. 3, 2021.

A petitioner may establish causation by showing that she suffered an injury contained in the Vaccine Injury Table corresponding to the vaccine she received within the appropriate timeframe. 42 U.S.C. §§ 300aa-13(a)(1)(A), § 300aa-11(c)(1)(C)(i), § 300aa-14(a), § 300aa-13(a)(1)(B). In such a case, causation is presumed. Id. To satisfy the elements for an on-Table SIRVA claim, a petitioner must show that (1) she had no history of shoulder pain prior to vaccination, (2) the onset of pain occurred within 48 hours after vaccination, (3) the injury is confined to the shoulder in which she received the vaccine, and (4) there is no evidence of any alternative cause of her pain. 42 C.F.R. § 100.3(a), (c)(10)(i)-(iv).

For the reasons listed below, Ms. McLee has failed to demonstrate that she suffered an on-Table SIRVA, and therefore is not entitled to compensation.

# A. History of Shoulder Pain

Ms. McLee has established that she had no history of shoulder pain prior to vaccination. The Secretary also concedes this point. The Secretary's report avers

that Ms. McLee's medical history does not indicate that she experienced any upper extremity pain prior to vaccination. Resp't's Rep., filed Nov. 19, 2021, at 3. Based on the medical records submitted by Ms. McLee, the first time Ms. McLee complained of shoulder pain to a medical professional was on December 9, 2017, approximately ten weeks after she received the flu vaccine. CM/ECF 18-2, at pdf 4. Although Ms. McLee has satisfied one element required to prove an on-Table SIRVA claim, other aspects of her SIRVA claim fail.

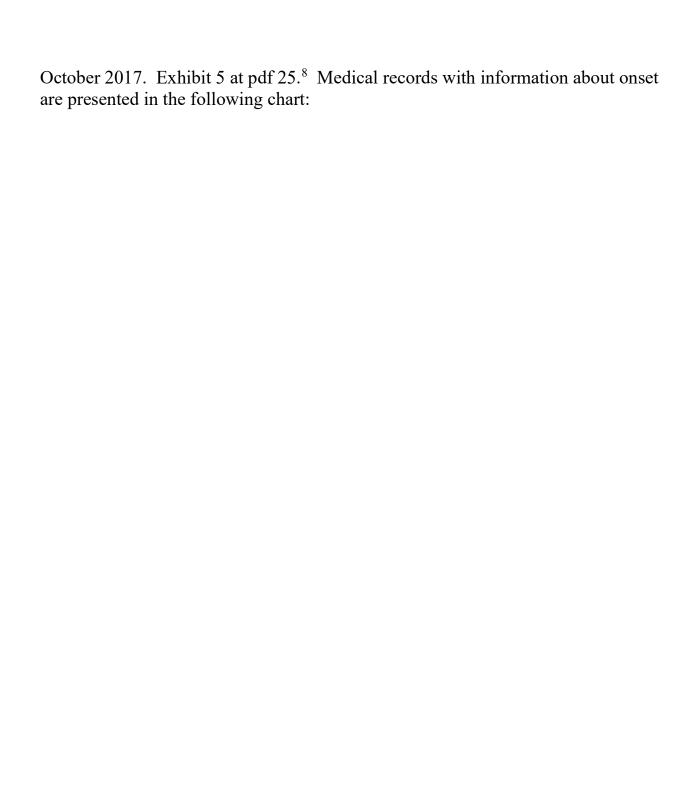
#### **B.** Onset of Pain Occurring Within 48 Hours

Under 42 C.F.R. § 100.3(c)(ii), Ms. McLee must demonstrate that her symptoms began within 48 hours of her vaccine. See 42 C.F.R. § 100.3(a) XIV.B. (2017) (shoulder injury from influenza vaccination). The "Qualifications and Aids to Interpretation" (QAI) for a SIRVA-based claim also require that onset occurs within a 48-hour time frame. 42 C.F.R. § 100.3(c)(10).

Ms. McLee offers some support for her assertion that her onset of symptoms began around the time of her flu shot. The medical record from January 29, 2018, indicates that Ms. McLee had a four-month history of pain, which would date back to late September 2017. CM/ECF 18-2 at pdf 19. Although this one record appears to support the onset of symptoms within the relevant timeframe of receiving the flu vaccine, three other records state that Ms. McLee's pain began *before* the date of vaccination. The medical record of January 24, 2018 notes that she reported increased pain in her left shoulder after the flu shot, but lists the date of onset as September 18, 2017. CM/ECF 20-8 at pdf 12. Similarly, the record of February 6, 2018, states that onset was "mid September," and the record of March 27, 2018 reports that the pain started on September 17, 2017. Exhibit 5 at pdf 27; CM/ECF 28 at pdf 50.

In contrast, the records created closest in time to Ms. McLee's vaccination place the onset of pain in October or November 2017. The medical records from December 9, 2017; two records from December 13, 2017; and records from January 16, 2018, indicate that Ms. McLee's left shoulder pain began in late October or November 2017. CM/ECF 18-2 at pdf 4, 18; Exhibit 3 at pdf 1, 7. The medical record from her visit on January 3, 2018, indicates that her pain began in

<sup>&</sup>lt;sup>7</sup> The medical record from Ms. McLee's April 27, 2018, appointment at the Hand and Upper Extremity Center states that she attributes her pain to a flu shot received in September 2017, but does not specify a timeframe for the onset of pain. Exhibit 8 at pdf 1.



<sup>&</sup>lt;sup>8</sup> The medical records filed with CM/ECF 42, which was stricken from the record, were reviewed by the undersigned and do not specify a date for the onset of pain.

Date of	Information from	Reported Onset	Record Citation
Record	Record		
12/09/2017	"L shoulder pain x 1 month"	November 9, 2017 (implied)	CM/ECF 18-2 at pdf 4
12/13/2017	"one month history of left arm pain"	November 13, 2017 (implied)	Ex. 3 at pdf 1
12/13/2017	"over the last 1 ½ months"	Late October 2017	Ex. 3 at pdf 7
01/03/2018	"developing slowly since October"	October 2017	Ex. 5 at pdf 25
01/16/2018	"2 months ago on 11/20/17"	November 20, 2017 (implied)	CM/ECF 18-2 at pdf 18
01/24/2018	"Date of Onset: 9/18/17"	September 18, 2017	CM/ECF 20-8 at pdf 12
01/29/2018	"four-month history of pain"	September 29, 2017(implied)	CM/ECF 18-2 at pdf 19
02/06/2018	"It began in mid September"	Mid-September 2017	Ex. 5 at pdf 27
03/27/2018	"When did the pain start? 9/17/2017"	September 17, 2017	CM/ECF 28 at pdf 50

In Ms. McLee's onset affidavit, initially filed on March 30, 2022, more than four and a half years after receiving the vaccination, she disputes the accuracy of some of these records. See CM/ECF 53-2. Ms. McLee's and witnesses' statements regarding onset are entitled to consideration. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1381-84 (Fed. Cir. 2021). However, contemporaneously created medical records are presumed to be accurate and are generally more reliable than later recollections. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Furthermore, Ms. McLee concedes there are no nurses' notes or medical records that confirm her recollection. Pet'r's Mot., at 2. Therefore, the medical records from December 9,

2017; December 13, 2017; January 3, 2018; and January 16, 2018, are more reliable than Ms. McLee's and her family's recollections over four years later. Additionally, Ms. McLee waited over 10 weeks post-vaccination to seek medical care for her left shoulder pain. Accordingly, Ms. McLee's assertion that the onset of shoulder pain began immediately after vaccination is unsupported by the majority of the medical records. See Cucuras, 993 F.2d at 1528. Thus, I find that Ms. McLee began experiencing shoulder pain in early November 2017. Ms. McLee has not shown that her injury occurred within 48 hours of her September 27, 2017 vaccination. CM/ECF 18-2 at pdf 4.

# C. Discrepancy Between Site of Vaccination and Location of Injury

## 1. Site of Vaccination

The third SIRVA criteria, 42 C.F.R. § 100.3(c)(iii), requires that "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." See also Dawson v. See'y of Health & Hum. Servs., No. 19-278V, 2021 WL 5774655, at \*3 (Fed. Cl. Nov. 4, 2021) ("To be sure, if a petitioner does exhibit reduced or limited range of motion under the QAI to establish a Table SIRVA any reduced range of motion must be 'limited to the shoulder in which the intramuscular vaccine was administered." (quoting Portee v. Sec'y of Health & Hum. Servs., No. 16-1552V, 2018 WL 5284599, at \*11 (Fed. Cl. Sept. 14, 2018))).

Ms. McLee claims that she received the flu vaccine in her left shoulder, and immediately began to experience pain. CM/ECF 53-2 (Onset Aff.) at pdf 2. However, her medical records indicate that she received the flu vaccine in her right deltoid. Exhibit 2A at pdf 1. Ms. McLee disputes the accuracy of these records, maintaining that she received the vaccine in her left deltoid. Exhibit 5 at pdf 32 (request for amendment of medical records); CM/ECF 53-2 (Onset Aff.) at pdf 3. Although she requested a "record correction," it was not provided. <u>Id.</u>

Ms. McLee's argument that the discrepancies are due to deceptions and/or fake assessments by her treaters is unpersuasive. Ms. McLee did not state that she received the vaccine in her left arm until January 16, 2018, when she reported that

<sup>&</sup>lt;sup>9</sup> Because the regulation requires shoulder pain to start within 48 hours of the vaccination, which was September 27, 2017, identifying a more specific date in November is not required.

she "developed the onset of pain [in her left shoulder] 2 months ago on 11/20/17 after receiving a flu shot." CM/ECF 18-2 at pdf 18. This was also the first record in which she attributed her pain to the flu vaccine. At subsequent medical and physical therapy appointments, Ms. McLee continued to attribute the pain in her left arm and hand to her flu vaccine. See, e.g., CM/ECF 18-20 at pdf 44 (January 24, 2018 physical therapy record stating onset of pain was following flu shot); pdf 19 (January 29, 2018 record reporting Ms. McLee's belief that pain started after flu shot); pdf 31 (April 27, 2018 record stating Ms. McLee attributed pain to flu shot).

However, on August 13, 2019, Ms. McLee visited MedExpress for "swelling to right shoulder after flu shot 2 years ago," and informed the doctor that she had been careful with the arm since then. CM/ECF 18-2 at pdf 15; CM/ECF 28 at pdf 13-14. Her right arm was X-rayed. <u>Id.</u> Importantly her tuberculosis skin tests on May 4, 2006, May 10, 2006, and April 29, 2008, have been administered in her right arm. Exhibit 2. Ms. McLee has not persuasively shown why she deviated this pattern for the allegedly causal flu vaccine.

Like Schmidt and Hanna, here, no hearing was held regarding the issue of the site of the vaccination. Schmidt v. Sec'y of Health & Hum. Servs., No. 17-1530V, 2021 WL 5226494 (Fed. Cl. Spec. Mstr. Oct. 7, 2021); Hanna v. Sec'y of Health & Hum. Servs., 2021 WL 3486248 (Fed. Cl. Spec. Mstr. 2021). Contemporaneously created medical records are presumed to be accurate and are generally more reliable than later recollections. See Cucuras, 993 F.2d at 1528. Thus, even though Ms. McLee "may honestly believe that [she] received the vaccine alleged as causal in [her] left arm, the record as it now stands preponderantly supports the opposite." Schmidt, at \*11. Accordingly, absent additional medical records or physician statements noting Ms. McLee's vaccination occurred in her left arm, having reviewed the materials in this record, the undersigned finds she received the flu vaccine in her right arm.

## 2. Confinement of Injury to Shoulder

Next, even if the vaccine was administered in the left shoulder as Ms. McLee alleges, her pain and reduced range of motion were not limited to this shoulder. In contrast, the medical records consistently reflect that Ms. McLee's left shoulder pain extended to her hand, fingers, and neck. See Exhibit 3 at pdf 7 (progressive weakness in the left upper extremity, across the neck and over both biceps and triceps, with numbness on all five fingers on the left hand); CM/ECF 18-2 at pdf 28-29 (diffuse neck pain traveling into the left shoulder and arm); Exhibit 8 at pdf 1 (constant throbbing pain in her left upper arm that sometimes

radiated to her neck); Exhibit 3 at pdf 1 (perceived weakness in left hand); CM/ECF 18-2 at pdf 19 (history of left shoulder and upper arm pain as well as tingling and numbness in the forearm and fingertips). Thus, the medical records show that Ms. McLee's pain was not limited exclusively to her left shoulder. Further, Ms. McLee states in her affidavit that her "entire left arm was in pain from 9/27/2017." CM/ECF 53-2 (Onset Aff.) at pdf 4 (emphasis added). Therefore, Ms. McLee has failed to establish that her injury was limited to her left shoulder.

Special masters have found that petitioners met their burden under SIRVA when reports of pain and injury extending beyond the shoulder were limited. See, e.g., Meagher v. Sec'y of Health & Hum. Servs., No. 18-1572V, 2023 WL 2582683, at \*6 (Fed. Cl. Mar. 21, 2023) (finding that "a single notation by a physical therapist, not a physician, documenting an isolated subjective report by petitioner that 'sometimes pain radiates all the way to R hand' and that 'over time pain has radiated into arm  $\rightarrow$  hand'" did not defeat SIRVA claim); K.P. v. Sec'y of Health & Hum. Servs., No. 19-0065V, 2022 WL 3226776, at \*7 (Fed. Cl. May 25, 2022) (finding that petitioner met SIRVA criteria where, although "at the first medical encounter, Petitioner reported that her severe pain also involved her left forearm and left hand," there was "no subsequent evidence of an injury extending beyond the shoulder.").

However, where, as here, the records *consistently* note pain and injury extending beyond the shoulder, special masters have found that petitioners did not meet the SIRVA criteria. See, e.g., Wood v. Sec'y of Health & Hum. Servs., No. 19-0189V, 2020 WL 8368926, at \*7 (Fed. Cl. Nov. 24, 2020) (finding that petitioner failed to meet the third SIRVA criteria where the records "contain numerous instances when Petitioner describes her pain as radiating into her chest and/or down her arm. She also describes pain in her neck and back."); Johnson v. Sec'y of Health & Hum. Servs., No. 20-1008V, 2022 WL 1613647, at \*2 (Fed. Cl. Apr. 7, 2022) ("Petitioner cannot establish that he suffered a Table SIRVA injury, given that his post-vaccination arm pain was not limited to his shoulder, but was consistently described as including: numbness in his fingers and hands, and paresthesia of the right upper extremity.").

Special masters have resolved whether pain was limited to a vaccine shoulder based upon the written record. See Johnson, 2022 WL 1613647, at \*2 (finding that petitioner failed to prove SIRVA where his arm pain also included numbness of the fingertips and paresthesia in the right upper extremity without going to a hearing); Wood, No. 19-0189V, 2020 WL 8368926, at \*7 (finding that, based on the record and without holding a hearing, that petitioner did not meet the

third SIRVA criteria where her pain extended beyond her shoulder); <u>Colbert v. Sec'y of Health & Hum. Servs.</u>, No. 18-166V, 2022 WL 2232210, at \*4, \*17 (Fed. Cl. Spec. Mstr. May 27, 2022) (finding that the parties had a fair opportunity to present their cases without a hearing and that petitioner did not satisfy the third criteria of SIRVA where she had "voiced subjective complaints demonstrating that she experienced pain beyond the left shoulder").

#### D. No Alternate Cause of Pain

Whether Ms. McLee's shoulder problem could have been caused by something other than the flu vaccine is not clear. The medical records reveal that frequent typing at work aggravated Ms. McLee's shoulder. See CM/ECF 18-2, at pdf 4. Physical therapy records show that Ms. McLee stated that typing at work all day increased her symptoms. CM/EF 20-8, at pdf 4. To understand the significance of these medical records, expert testimony about the potential consequences to prolonged typing might have been helpful. The parties, however, have offered no such opinion.

#### V. Off-Table Shoulder Injury

Thus, Ms. McLee cannot prevail on her Table claims for SIRVA. She may, however, continue to pursue a claim for an off-Table shoulder injury. The pleadings of pro se petitioners are held to less stringent standards than those of petitioners represented by counsel. See Fesanco v. Sec'y of Health & Hum. Servs., 99 Fed. Cl. 28, 32 (2011). "Indeed, it has been the tradition of this court to examine the record to see if [a pro se] Plaintiff has a cause of action somewhere displayed." Id. (internal quotation marks omitted). Although Ms. McLee predominantly references SIRVA in her filings, she alleges "injuries including Guillain Barre Syndrome." Am. Pet. at Preamble. Reading this broadly, Ms. McLee has alleged off-Table shoulder injuries.

Petitioners who allege an off-Table injury bear the burden "to show by preponderant evidence that the vaccination brought about [their] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Schick-Cowell v. Sec'y of Health & Hum. Servs., No. 18-656V, 2022 WL 619839, at \*9 (Fed. Cl. Feb. 8, 2022) (quoting Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005)).

That Ms. McLee has alleged an on-Table SIRVA claim does not satisfy her burden under the first prong; she must present a medical theory causally connecting the vaccination and an off-Table shoulder injury. <u>Id. See also Grant v. Sec'y of Dep't of Health & Hum. Servs.</u>, 956 F.2d 1144, 1148 (Fed. Cir. 1992). If Ms. McLee wishes to pursue a claim for an off-Table injury, she is expected to retain an expert to provide a report supporting her allegations and presenting a theory of causation.

As for the second prong, while Ms. McLee's own statements attributing her shoulder and arm pain to the flu shot are entitled to consideration, these alone do not support a logical sequence of cause and effect. <u>Id.</u> at \*11. Ms. McLee will need to present additional evidence, such as statements from treating physicians, to satisfy her burden under this prong.

Finally, the undersigned has determined that the onset of Ms. McLee's injury was in early November, 2017. Ms. McLee must establish that this temporal relationship supports her theory of causation.

If Ms. McLee wishes to continue litigating this case, she is ordered to file a status report within 60 days through CM/ECF confirming that she has retained an expert. If Ms. McLee does not do so, her off-Table claim will be dismissed.

#### VI. Conclusion

Ms. McLee has not satisfied the elements for a Table SIRVA claim. Thus, this claim is dismissed for unpersuasive evidence. However, she should have the opportunity to prove her off-Table claim by obtaining and offering expert support. Accordingly, the following is ORDERED:

Ms. McLee may file a status report by **Wednesday**, **July 12**, **2023** (1) confirming that she has retained a competent expert, (2) identifying the expert, and (3) proposing a deadline for submitting the expert's report.

IT IS SO ORDERED.

S/Christian J. Moran Christian J. Moran Special Master